

## REMARKS

Claims 1-34 are pending in the present application. Claims 1 and 10 have been amended. No new matter has been added to the application. Claims 19-34 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

### *Rejections under 35 U.S.C. §112*

#### I. Enablement

Claims 1-31 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. Applicants respectfully traverse. The Office Action states that the specification is enabled for reducing plaque or plaque build-up and gingivitis; however, the Office Action states that the specification does not enable preventing plaque, plaque build-up, and gingivitis.

In the instant application, “the term ‘preventing plaque’ means precluding the development of plaque on and around the exposed portions of teeth or reducing the risk of plaque forming on and around the exposed portions of teeth.” ¶[0021] (All citations to the instant specification are to the US publication US2007/0264291). Further, “the term ‘preventing plaque build-up’ means precluding the development of plaque which remains on teeth after one or more routine brushings of the teeth or reducing the risk of plaque remaining on the teeth after one or more routine brushings of the teeth;” (¶[0023]) and “‘preventing gingivitis’ means precluding the development of inflammation of the gums or gingiva due to bacteria-containing plaque on one or more adjacent teeth or reducing the risk of inflammation of the gums or gingiva due to bacteria-containing plaque on one or more adjacent teeth.” ¶[0026].

Example 2, which is discussed in detail in paragraphs 72-75 of the instant specification, provides data showing the prevention and reduction of plaque, plaque build-up, and gingivitis as these terms are defined in the specification. As detailed in the specification, all subjects received supragingival prophylaxis prior to beginning the study to remove all plaque, calculus and extrinsic stain and create a baseline for each of the subjects. The levels of Silness & Loe Plaque Index (PLI) and Gingival Bleeding Index (PBI) were measured and recorded at baseline (BL) to have a value to compare to the values measured at the end of the

six week study period. The subjects were instructed to brush with their assigned dentifrice (either control or test) and toothbrush. The control dentifrice was the non-aqueous formulation of Table II without any bioactive glass particulate. Abrasive silica was added instead of the NovaMin® particles in the control. The experimental dentifrice was formulated as a non-aqueous paste containing 5% by weight of bioactive glass particles with an average particle size of 12  $\mu\text{m}$ . The experimental composition is detailed in Table II. At the end of the six week period, the PLI and PBI levels were again measured for the study subjects. A Student t-test was used to compare the effect between the test and control groups, p value was set at 5% level.

The table below shows the results of the study in tabular form. The same data is found in the specification in narrative form.

	PLI	PBI
Baseline (test)	$1.54 \pm 0.34$	$1.14 \pm 0.79$
6 week (test)	$1.29 \pm 0.40$	$0.47 \pm 0.36$

	PLI	PBI
Baseline (control)	$1.60 \pm 0.37$	$1.18 \pm 0.76$
6 week (control)	$1.57 \pm 0.41$	$1.02 \pm 0.56$

As can be seen, for the control group, there was essentially no difference in results between baseline and after six weeks for PLI and PBI. In contrast, the PLI in the test group was reduced from 1.54 to 1.29, for a reduction of about 16.4%; and the PBI for the test group was reduced from 1.14 to 0.47, for a reduction of about 58.8%. What this data shows is that the test dentifrice prevents new plaque, plaque-buildup, and gingivitis and also reduces or decreases any old or existing plaque, plaque build-up, and gingivitis.

Based on the foregoing, Applicants submit that the specification is enabling for the prevention and reduction of plaque, plaque build-up, and gingivitis. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

## II. Indefiniteness

Claims 1-34 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse. In particular, the Office Action states that the phrase "less than about" is indefinite. Applicants have amended claims 1 and 10 to

replace the phrase "less than about" with the phrase "less than" (i.e., the term "about" has been deleted). Applicants submit that amended claims 1 and 10 and any claims depending therefrom are not indefinite. As such, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

***Rejections under 35 U.S.C. § 103***

Claims 1-34 were rejected under 35 U.S.C. § 103 as being unpatentable over Gates, US 5,882,630 ("Gates") in view of Litkowski et al., WO 99/13852 ("Litkowski"). Applicants respectfully traverse. Claims 19-34 have been cancelled. Thus any rejection thereof is now moot.

Amended claim 1 recites a method for preventing or reducing plaque or plaque build-up in an individual comprising contacting all or a portion of the individual's oral cavity with a non-aqueous composition comprising a carboxyvinyl polymer, a humectant, a polyethylene glycol and about 0.25 to about 10% by weight bioactive glass particles having an average particle size of less than 20 microns for a time effective to prevent or reduce plaque or plaque build-up.

Amended claim 10 recites a method for preventing or reducing gingivitis in an individual comprising contacting the individual's oral cavity with a non-aqueous composition comprising a carboxyvinyl polymer, a humectant, a polyethylene glycol and about 0.25 to about 10% by weight bioactive glass particles having an average particle size of less than 20 microns for a time effective to prevent or reduce gingivitis.

Applicants submit that claims 1 and 10 and the claims depending therefrom are not obvious in view of the combination of Gates and Litkowski because the combination does not disclose or reasonably suggest all of the limitations of the claims. Gates discloses a non-aqueous dentifrice composition that is suitable as a vehicle for materials that are incompatible with an aqueous environment. *See*, Abstract. However, Gates provides no disclosure regarding bioactive glass. Litkowski discloses methods for whitening teeth including contacting teeth with particulate bioactive glass. *See*, Abstract. However, Litkowski provides no disclosure regarding the use of bioactive glass to prevent or reduce plaque, plaque build-up, and/or gingivitis. Rather, Litkowski is directed solely to teeth whitening, including bleaching, lightening, or removing stain from teeth. *See*, p. 2, ll. 24-25. As such, neither Gates, Litkowski, nor the combination thereof discloses or reasonably suggests a method for preventing or reducing plaque, plaque build-up, and/or gingivitis using a

composition comprising bioactive glass as recited in claims 1 and 10, respectively. Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

For the foregoing reasons, claims 1-18 are considered to be allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

**The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 23-1925.**

Respectfully submitted,

BRINKS HOFER GILSON & LIONE

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By: Allyn B. Rhodes  
Allyn B. Rhodes  
Registration No. 56,745

2801 Slater Road, Suite 120  
Morrisville, NC 27560-8477  
Phone: 919.481.1111  
757381v1